## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.

09/895,027

Applicant(s)

Olaf Isele, et al.

Filed

June 29, 2001

Title

Top-Biased Beneficial Components On Substrates

TC/A.U.

1615

Examiner

Lakshmi S. Channavajjala

Conf. No.

7458

Docket No.

8610

Customer No.

27752

## **DECLARATION UNDER 37 C.F.R.§1.132**

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Washington, D.C. 20231

## Dear Sir:

I, Olaf Isele, of Cincinnati, Ohio, the undersigned, hereby declare as follows:

All statements made herein are true to the best of my knowledge, or, if made upon information and belief, are believed to be true.

I am a graduate of University of Wisconsin-Madison having received a Master of Science degree in Chemical Engineering from said institution in 1992. I have been employed by The Procter & Gamble Company of Cincinnati, Ohio (including wholly owned subsidiaries), the assignee of the present application, from 1993. During this time, I have worked in the areas of diaper process development, material (film and nonwovens) development, and skin care programs in diaper design, including lotion development, converting and product analysis.

I am a co-inventor of the above-referenced application (hereinafter "Application"). Accordingly, I am familiar with the subject matter, including the claims of the Application.

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I am familiar with the content of International Publication Number WO 00/64502 issued to Krzysik et al. (hereinafter "Krzysik"). Krzysik has been cited by the Examiner against the claims of the present application in several Office Actions including the latest dated June 29, 2005.

Important and critical differences exist between Krzysik and the Application. Krzysik explains migration and desire to avoid migration in a limited and incomplete fashion. Krzysik measures how much "lotion" is retained in the body-side liner at higher vs. lower temperature storage conditions. This means that, if the underlying core-material has a higher affinity (e.g., surface energy and capillarity) to the lotion than the body-side liner, the test will show a disadvantage (e.g., lotion migration from the body-side liner). Vice versa, the Krzysik test may show an advantage with the lotion remaining in the body-side liner if the liner has higher affinity, even when all lotion is sitting in the body side liner at the interface to the core material and away from the wearer's skin.

However, Krzysik does not show that the "lotion" (e.g., a beneficial component) will preferably sit on top (e.g., nearer to the wearers skin) of the body side liner with a higher concentration that is ready to be released. In Krzysik, migration means the lotion has left the liner. In our Application, migration means transport through the thickness of the substrate and away from the point from which lotion is transferred to consumer (or target surface). In Krzysik, low migration means lotion is somewhere in the liner, including possibly immobilized and not available for transfer to the consumer or target surface. In our application, low migration means maintenance of the top biasing effect, and lotion is available for transfer. We discovered the significance of this top-bias beyond just mere minimization of migration (in the Krzysik context) and developed ways to achieve it.

Top bias is related to the necessity of providing the benefit of the beneficial composition to the consumer. Our top bias definition states that after production, storage, and until the time of use, a 'majority' of the lotion is in or on the top-part (e.g., top third) of the body-side liner. This top bias definition is a limitation present in Claim 1 of the Application. The "Z-migration" test by Krzysik, as described above, does not teach top-biasing. Top-biasing is manifest when the lotion is applied in such manner that the lotion

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is not exhibiting high affinity to the topsheet and likelihood of spreading, such as by using a first and second layer.

Further, the top bias measurement is the best test short of actually having a wear or transfer test with a consumer, which is a highly variable, unreliable and expensive test method.

In conclusion, the Application is directed to maximizing top-bias, rather than just minimizing migration, in order to have lotion readily available near and transferable to the wearer's skin (or other target surface).

Further declarant sayeth not.

This declaration is made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001, and may jeopardize the validity of the above-captioned patent application or any patent issuing thereon.

10/31 / 2005 Date

(Claf Isele

18 U.S.C. §1001 Whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or advice a material fact, or makes any false, fictitious or fraudulent statement or representation, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry, shall be fined not more than \$10,000 or imprisoned not more than five years, or both.